K023503
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510(k) Summary

SUBMITTED ON BEHALF OF:

Company Name:	**Leonhard Lang GmbH**
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by: Elaine Duncan, MS.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
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CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: October 16, 2002

Trade Name: Skintact® ECG Electrode
Common Name: Disposable ECG Electrodes
Classification Name: Electrocardiograph (ECG) electrode

SUBSTANTIALLY EQUIVALENT TO: Skintact® ECG Electrodes with solid adhesive gel are substantially equivalent to the Skintact® ECG Electrodes with liquid gel (the manufacturer's predicate device cleared under K982521). FDA previously cleared predicate solid adhesive gel electrodes in K960968.

DESCRIPTION of the DEVICE: Skintact® ECG Electrodes *(and as also to be offered for sale under various private label tradenames)* will now also be offered with solid adhesive gel. Just like the liquid gel electrodes, solid adhesive gel electrodes are self-adhesive, non-sterile, single use disposable snap electrodes. The solid adhesive electrodes are identical in size, shape and configuration to the liquid gel Skintact ECG electrodes currently marketed by Leonhard Lang, GmbH.

All electrode configurations include a stainless steel stud to guarantee an unimpaired performance during the shelf-life of the product. All electrodes include an ABS sensor element coated with silver. The silver layer is either completely or partially (in the areas in contact with the conductive gel) covered with a silver chloride layer. This is the same construction as the current Skintact® ECG electrode using liquid gel conducting media.

INDICATIONS FOR USE:

Skintact ECG electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording. Skintact ECG electrodes are non-sterile and are to be used on intact (uninjured) skin. (NO CHANGE to ORIGINAL INDICATION for USE)

SUMMARY of TESTING:

Biocompatibility testing confirms the materials are biocompatible and the change does not introduce new risks. The following testing showed no adverse results: Cytotoxicity; Skin Irritation; Sensitization.

The ANSI/AAMI EC 12:2000 "Disposable ECG electrodes" was used to define the requirements for Skintact ECG Electrodes with solid adhesive gel. All electrical tests are according to ANSI/AAMI EC 12:2000. A certification to conformance **EC12:2000** with this standard has been provided. The testing conducted was: AC impedance; DC offset voltage; Defibrillation overload recovery; Combined offset instability and internal noise; Bias current tolerance.

The shelf life of the electrodes with solid adhesive gel was tested in real-time aging and in accelerated aging. For accelerated aging the electrodes were in an incubator for a time of 3 months with an increased temperature of 40°C. In accelerated shelf life testing the electrodes are subjected to a controlled environment in which one or more extrinsic factors (e.g., temperature, humidity, gas atmosphere, light) is maintained at a higher than normal level. Leonhard Lang has experience for about 20 years of using the current packaging and this ensures all requirements for the 24 months shelf-life of the electrodes. No differences were required for packaging of the solid adhesive electrodes compared to the predicate electrode.

The results of these tests confirm that the shelf-life of Leonhard Lang Skintact ECG Gel Electrodes with solid adhesive gel is well inside the limits defined in ANSI/AAMI EC12-2000, both for the first test and with real-time and accelerated aged electrodes. Thus the conclusion that the electrical performance of the solid adhesive gel electrodes will stay within the limits during their shelf-life of 24 months. The comparison with the predicate device and the data from the solid adhesive gel electrodes shows similar results. The difference is negligible in the limits defined in ANSI/AAMI EC12-2000. Therefore electrical performance of the predicate device and solid adhesive gel electrodes is equivalent.

Clinical data: The potential effect of material change to the conducting signal was evaluated by repeating the clinical trace testing per the FDA guidance on the solid adhesive gel and determined that the solid adhesive gel performs the same. Comparing the ECG traces between solid adhesive gel and liquid gel electrodes demonstrate that solid adhesive gel electrodes are equivalent to the liquid gel electrodes. Three wear test reports for Holter monitoring electrodes used for 48 hours were provided. A physician reviewed the performance of the wear tests and examined for skin irritation. The tests confirm that the performance of electrodes is quite good and that wearing of the electrodes does not cause any skin problems for the volunteers. During a time of 48 hours there was no deterioration of electrical performance and the gel did not dry out. The electrodes were not replaced during this time and did not show any displacement; although the volunteers worked and participated in sports as usual demonstrating the adhesion was also very good. (No change to adhesive formulation was made.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Leonhard Lang GmbH
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082-0560

Re: K023503
Trade Name: Skintact ECG Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: October 16, 2002
Received: October 18, 2002

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K023503

Device Name: Skintact ECG Electrodes

Indications for Use:

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(Please Do Not Write Below This Line-Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

K023503

Division of Cardiovascular & Respiratory Devices

510(k) Number E Miller